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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/656,129	09/08/2003	Fukushi Hirayama	02213.000300.1	8648

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EXAMINER	
COLEMAN, BRENDA LIBBY	
ART UNIT	**PAPER NUMBER**
1624	

DATE MAILED: 12/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/656,129	HIRAYAMA ET AL.	
	Examiner	Art Unit	
	Brenda L. Coleman	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 10/148,544.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *9/03 & 6/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-7 are pending in the application.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

1. Claims 1-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following reasons apply:

a) Claims 1-7 are vague and indefinite in that it is not known what is meant by "derivative" which implies more than what is positively recited. "Compound" is suggested.

b) Claim 1 and claims dependent thereon are vague and indefinite in that a formula is not general when all of the variables are defined. Deletion of "general" is suggested.

c) Claim 1 and claims dependent thereon are vague and indefinite in that the claim does not end with a period but rather a close parenthesis.

d) Claim 1 and claims dependent thereon are vague and indefinite in that it is not known what is meant by the definition of "R"ings A and B, which contains a capital letter.

608.01(m) Form of Claims [R - 3]

>The claim or claims must commence on a separate sheet and should appear after the detailed description of the invention.< While there is no set statutory form for claims, the present Office practice is to insist that each claim must be the object of a sentence starting with "I (or we)

claim", "The invention claimed is" (or the equivalent). If, at the time of allowance, the quoted terminology is not present, it is inserted by the clerk. Each claim **begins with a capital letter** and ends with a period. Periods may not be used elsewhere in the claims except for abbreviations. See Fressola v. Manbeck, >36 USPQ2d 1211< (D.D.C. 1995). ** >Where a claim sets forth a plurality of elements or steps, each element or step of the claim should be separated by a line indentation, 37 CFR 1.75(i).<

e) Claim 6 is vague and indefinite in that it is not known what is meant by a pharmaceutical composition, which fails to include a pharmaceutically acceptable carrier.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1, 3, 4, 6 and 7 are rejected under 35 U.S.C. 102(e) as being anticipated by HERRON et al., U.S. Patent Application Publication No. 2004/0097491. HERRON teaches the compounds, compositions and method of use of the compounds of formula (I) where R^1 is H, Me, Et, etc.; ring B is pyridinyl, pyridazinyl, pyrimidinyl, pyrazinyl, etc.; X^2 is –NH-C(=O)-; R^2 is F, Cl, CO_2H, CO_2Me, etc.; R^3 is H, F, etc.; X^1 is -NH-C(=O)-; ring A is 5-chloro-2-pyridinyl, 5-methyl-2-pyridinyl, 5-fluoro-2-pyridinyl, etc. See examples 1-8, 10-16, 20, 22-27, 30-38, 47, 49, 50, 56-60, 62, 63, 66-69, 71-73, etc.

3. Claims 1, 3, 4, 6 and 7 are rejected under 35 U.S.C. 102(e) as being anticipated by HERRON et al., U.S. Patent Application Publication No. 2004/0097491. HERRON teaches the compounds, compositions and method of use of the compounds of formula (I) where R^1 is H, Me, etc.; ring B is phenyl, etc.; X^2 is –NH-C(=O)-; R^2 is F, Cl, etc.; R^3 is H, etc.; X^1 is -NH-C(=O)-; ring A is 5-chloro-2-pyridinyl, 5-methyl-2-pyridinyl, etc. See examples 1, 2, 4-6, 9-15, 17-22, etc.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 1-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over HERRON et al., U.S. Patent Application Publication No. 2004/0097491. The generic structure of HERRON encompasses the instantly claimed compounds (see Formula I) and for the same uses as claimed herein. Examples 1-8, 10-16, 20, 22-27, 30-38, 47, 49, 50, 56-60, 62, 63, 66-69, 71-73, etc. differ only in the nature of the Q, L, R, X^1, X^2, X^3 or X^4 substituents. Column 2, paragraph [0010] through paragraph [0027] defines the variables Q, L, R, X^1, X^2, X^3 or X^4 as follows: L is carbonyl or methylene and Q is a residue of formula Q^A; one or two of X^1, X^2, X^3 and X^4 is N; and each of the others of X^1, X^2, X^3 and X^4 is CH; and R is hydrogen, (1-3C)alkyl, (1-3C)acyl, acetyloxy-acetyl, etc. Compounds of the instant invention are generically embraced by HERRON in view of

the interchangeability of the Q, L, R, X^1, X^2, X^3 and X^4 substituents of formula (I). Thus one of ordinary skill in the art at the time the invention was made would have been motivated to select for example phenyl or indolyl for ring A as well as other possibilities from the generically disclosed alternatives of the reference and in so doing obtain the instant compounds in view of the equivalency teaching outlined above.

It is recognized benefit of PCT/JP01/02673 filed March 29, 2001 as well as foreign priority of Japanese application 2000-096858 filed March 31, 2000 is being urged. However, the applicant's priority document does not describe the invention of this application serial number 10/656,129. Note for benefit under 35 USC 120 and 35 USC 119, there must be clear support (description and enablement) for claims instantly rejected herein as was set forth in In re Scheiber 199 USPQ 782; In re Lukach, 169 USPQ 795; In re Gostelli, 10 USPQ 2nd 1614; Kawai v. Metlesics 178 USPQ 159. The applicants' attention is drawn to the definition of X^1, R^1, R^2 and R^3.

5. Claims 1-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over HERRON et al., U.S. Patent Application Publication No. 2004/0058989. The generic structure of HERRON encompasses the instantly claimed compounds (see Formula I) and for the same uses as claimed herein. Examples 1, 2, 4-6, 9-15, 17-22, etc. differ only in the nature of the M, Q, L, R, R^1, A^1, A^2, A^3 or A^4 substituents. Column 2, paragraph [0010] through paragraph [0033] defines the variables Q, L, R, R^1, A^1, A^2, A^3 or A^4 as follows: L is carbonyl or methylene; M is N; and Q is a residue of formula Q^A; one or two of A^1, A^2, A^3 and A^4 together with the two carbons to which they are attached, complete a substituted benzene; R is hydrogen, (1-3C)alkyl, (3-5C)cycloalkyl,

(1-3C)acyl, acetyloxy-acetyl, etc.; and R^1 is 2-pyridinyl, phenyl, 6-indolyl or 6-indazolyl. Compounds of the instant invention are generically embraced by HERRON in view of the interchangeability of the M, Q, L, R, R^1, A^1, A^2, A^3 and A^4 substituents of formula (I). Thus one of ordinary skill in the art at the time the invention was made would have been motivated to select for example phenyl or indolyl for R^1 as well as other possibilities from the generically disclosed alternatives of the reference and in so doing obtain the instant compounds in view of the equivalency teaching outlined above.

It is recognized benefit of PCT/JP01/02673 filed March 29, 2001 as well as foreign priority of Japanese application 2000-096858 filed March 31, 2000 is being urged. However, the applicant's priority document does not describe the invention of this application serial number 10/656,129. Note for benefit under 35 USC 120 and 35 USC 119, there must be clear support (description and enablement) for claims instantly rejected herein as was set forth in In re Scheiber 199 USPQ 782; In re Lukach, 169 USPQ 795; In re Gostelli, 10 USPQ 2nd 1614; Kawai v. Metlesics 178 USPQ 159. The applicants' attention is drawn to the definition of X^1, R^1, R^2 and R^3.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422

F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 1-7 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-6 of U.S. Patent No. 6,642,224. Although the conflicting claims are not identical, they are not patentably distinct from each other because the compounds of U.S. '224 are embraced by the compounds of the instant invention where ring A is 4-methoxyphenyl, X^1 is -C(=O)-NH-; R^2 is OH; X^2 is -HN-C(=O)-; ring B is phenyl or pyridyl; and R^1 is lower alkyl.

7. Claims 1-7 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-8 of copending Application No. 10/399,625. Although the conflicting claims are not identical, they are not patentably distinct from each other because the compounds, compositions and method of use of the compounds of formula I of the instant invention are embraced by the compounds, compositions and method of use of the compounds of formula I of U.S. 625 where ring A is benzene ring or a five- or six-membered hetero ring containing 1 to 4 hetero atom(s) which is/are one or more selected from a group consisting of N, S and O; ring B is a benzene ring substituted with an R^8 substituted diazepine ring; X^1 is -

$C(=O)-NR^5-$, $-NR^5-C(=O)-$, $-CH_2-NR^5-$ or $-NR^5-CH_2-$; X^2 is $-C(=O)-NR^6-$, $-NR^6-C(=O)-$, $-CH_2-NR^6-$ or $-NR^6-CH_2-$; R^4 is H or $-SO_3H$; etc.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brenda L. Coleman whose telephone number is 571-272-0665. The examiner can normally be reached on 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Brenda Coleman

Brenda L. Coleman
Primary Examiner Art Unit 1624
December 6, 2005